Ipsos MORI is a data processor, acting on behalf of DHSC and Imperial College London. They will only keep your data in a way that can identify you for as long as is necessary to support the research project and findings. By June 2021 Ipsos MORI will delete your personal contact data from their systems.

If you consent to being contacted for future research, and/or for the results of this study being linked to other health information that the NHS holds about you, Imperial College London, may keep your data for up to 20 years in order to support this research. That includes the contact details you provide to Ipsos MORI. If you have consented to data linkage, we may receive your contact details from the NHS and, if you have consented to be contacted for future studies we may use them to contact you.

Researchers who wish to access the data from this study and/or to contact participants about future research will have to apply to a data access committee composed of at least 3 of the study investigators and at least one public representative.

Legal Basis

We use personally-identifiable information collected in this study to conduct research to improve health, care and services.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the **UK Policy Framework for Health and Social Care Research**.

Do you share my information with others?

There is more information about how your personal data will be used and stored in the study privacy policy: www.ipsos.uk/antibodyPrivacy

What are my choices about how my information is used?

You can stop taking part in the study at any time, without giving a reason, however once your data has been included with the rest of the study data and analysed, it is not possible to remove your specific data from the results.

Where can I find out more about how my information is used?

You can find out more about how your information is used at www.hra.nhs.uk/information-about-patients, or by asking one of the Research Team, by sending an email to UK-Covid-test-research@ipsos.com.

Our insurance statement

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you

should immediately inform the Investigators on UK-Covid-test-research@ipsos.com. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office.

How to make a complaint

If you wish to raise a complaint on how we have handled your personal data, please contact:

Ipsos MORI's Data Protection Officer via email at compliance@ipsos.com with "COVID-19 home testing (20-064338-01)" in the email subject line, and/or via post COVID-19 home testing (20-064338-01), Compliance Department, Market and Opinion Research International Limited, 3 Thomas More Square, London E1W 1YW, United Kingdom.

Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (Imperial College London) first before involving the regulator.

Additional contact details

If you have further questions before deciding whether to take part, please contact the Research Team, email **UK-Covid-test-research@ipsos.com**.

Thank you for considering taking part in this research.

Thank you

16/12/20



Imperial College London







COVID-19 in-home antibody testing research study

Information sheet for participants

IRAS No 283805 201216 Study 5 R5 PIS_v1.8 16/12/20 IRAS No 283805 201216 Study 5 R5 PIS_v1.8

This is an antibody research study. Antibodies are made by the immune system to fight infection. In this study, we will use the results of self-administered antibody tests to help us understand how many people in England have already been infected with the virus which causes COVID-19.

At this time, antibody testing results should not be used to alter individual behaviour as there is still a lot to learn about this virus and whether or not antibodies are important in preventing people from getting COVID-19 again.

Who is running this research?

This research is being run by doctors and researchers at Imperial College London and Ipsos MORI, an independent research organisation. The research is funded by Department of Health and Social Care (DHSC).

Why have I been invited to take part?

You have been invited to take part in this study because you registered to take part in response to our initial invitation letter and you are aged 18 years or over. The initial invitation was sent to your address after it was randomly selected from the NHS list of patients registered with a GP in England. This random selection method ensures that the data we collect gives us an accurate representation of the whole country.

What is involved?

In this study we are inviting you to read the instructions of the self-administered antibody kit and do the test on yourself at home. The test looks a bit like a pregnancy test but uses a drop of blood taken from your finger. Please read the instruction booklet sent with the test for detailed guidance on taking the test.

We are also asking you to go online to our secure internet portal to complete a short survey that will ask you to:

- 1. Record any COVID-19 symptoms you may have had in recent months
- 2. Provide feedback on your experience of using the self-administered antibody kit
- 3. Record your test result if completed
- 4. Upload a photograph of your test result if completed (this step is optional)

In total, this should all take around 45 minutes. It is very important that only the named person who registered to take the test and who was sent the testing kit takes the test.

If you do not have access to the internet, you can call the FREEPHONE number **0800 819 9150** and take part over the phone.

If you consent to being contacted again, we may contact you by phone or email 2 to 4 weeks after completing the antibody test to complete a short additional survey. We may re-contact people who report an IgG positive antibody test and a random sample of people who report a negative or IgM positive test result.

Will you need to collect any information about me?

We will need to collect some details about you, including your name, age, gender, and ethnicity. We will also ask for details of any previous tests you may have taken for COVID-19. We will ask you about the timing of any recent illness and what symptoms you may have had. As mentioned previously, we will also ask you about your experience of using the self-administered antibody kit, how easy it was to interpret the result using the instructions, and your confidence in reporting the result.

It is extremely important to us that we maintain your confidentiality about taking part in this study. All information collected about you will be used and stored securely to protect and respect your identity. Your data (the information collected about you) will be given a unique study number to make sure you cannot be identified from your data. Only the Research Team will be able to match your name to the unique study number, if it is necessary to do so.

There is more information about how your personal data will be used and stored in the study privacy policy: www.ipsos.uk/antibodyPrivacy

Do I have to take part?

No. Whether you take part in the study is entirely up to you. Even if you do decide to take part, you can change your mind at any time without giving a reason. You should be aware that data collected about you up to the time you decide to stop taking part may still be used as part of the research study results. If you have received the test and then decide you don't want to take part anymore, please throw away the testing kit as set out in the test instructions which come with the test.

Confidentiality

If you consent to take part in the research your name will not be shared outside the Research Team. We confirm that your personal data will never be available to the general public in any circumstances. The results of this research are likely to be published but will not contain any personal information which could identify you (i.e. name, age, gender, ethnicity). Please keep this information sheet for reference.

How will this research help others?

The study aims to estimate how many people in England have been infected with the virus that causes COVID-19. We don't know yet if having antibodies gives someone long-lasting protection from the virus. The results of this study may help guide public health policy and the government's plan for its antibody testing strategy.

The NHS urgently needs donations of blood plasma which could save lives. If your test result is positive, the NHS would very much like to hear from you. Please call 0300 123 23 23 or visit www.nhsbt.nhs.uk for further information and to register your interest.

What do the antibody test results mean?

Antibodies are made by the immune system to fight infection. This test looks for two types of antibodies, IgM, which are often short-lasting, and IgG, which are usually

16/12/20

longer lasting. By looking for antibodies in blood, we can understand whether someone has previously been infected with the virus that causes COVID-19.

Please be aware that the antibody test is not reliable at an individual level. Therefore, whatever your test result, you must continue to follow current Government advice.

Therefore, it is very important, despite what the results of this test shows that **you do not change your behaviour** in any way, as the test result may be incorrect. It is important that you continue to follow the current Government advice which is relevant to you.

What are the possible risks or side-effects of taking part?

Collecting the blood sample for the self-test requires a finger prick which can feel like a little pinch and which may cause some people a small amount of discomfort.

How do I take part?

If you are interested in taking part in this study, please go to the study website: https://www.reactstudy.org/antibodytest and enter the access code found in the test letter. Alternatively, you can call the FREEPHONE number **0800 819 9150** for assistance with completing the survey.

What will happen to the results of this research study?

Once analysed, the results of the study (which do not contain personal identifiable information) will be shared with the NHS, Public Health England, Department of Health and Social Care and scientists from the Research Team to help understand how many people in England have already been infected with the virus which causes COVID-19.

At the end of the study the results may be shared in many different ways, such as being published in medical journals, presented at meetings and reported to both Imperial College, London and the Health Research Authority who oversee and review how research takes place in England.

There is more information about how your personal data will be used and stored in the study privacy policy: www.ipsos.uk/antibodyPrivacy

Who has reviewed the study?

IRAS No 283805

To protect your interests, all research at Imperial College London is reviewed by an independent group of people called a Research Ethics Committee. This study has been reviewed and it has been granted 'favourable opinion' by the South Central Berkshire B Research Ethics Committee.

What will happen with the information I provide?

The Department for Health and Social Care (DHSC) and Imperial College London are joint data controllers for the processing of personal data for this survey, which means that they are responsible for ensuring that the processing complies with the General Data Protection Regulation (GDPR). You can access DHSC's Privacy Notice at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/800049/Privacy_Notice_v2_.pdf/ and Imperial's privacy policy at www.ipsos.uk/antibodyPrivacy

201216 Study 5 R5 PIS_v1.8

16/12/20

IRAS No 283805 201216 Study 5 R5 PIS_v1.8 16/12/20 IRAS No 283805 201216 Study 5 R5 PIS_v1.8



Coronavirus antibody test for research purposes only



Start here

This antibody test kit is part of a research study with Imperial College London. Please be aware that the antibody test is not 100% accurate. This means that although the test is not accurate enough to confirm whether or not an individual has had COVID-19, this research will allow us to estimate how many people in England have already been infected with the virus which causes COVID-19. This information will help the Government to plan its response.

Result of this test

We do not yet know if having antibodies against coronavirus stops people from getting COVID-19 again. Whatever your result, you must continue to follow current Government advice.

Here is what you will be asked to do as you go ahead with taking this test.

Read all of the information in the pack.

Organise the testing kit in a clean, safe space.

Follow the nine steps in this booklet.

Record your result and dispose of the kit.



The instructions in this booklet will guide you on how to take the test yourself. Although the test can be done alone, we advise you get someone from your household to assist you if you need.

If you have internet access you can watch a video explaining the steps at www.reactstudy.org/antibodytest

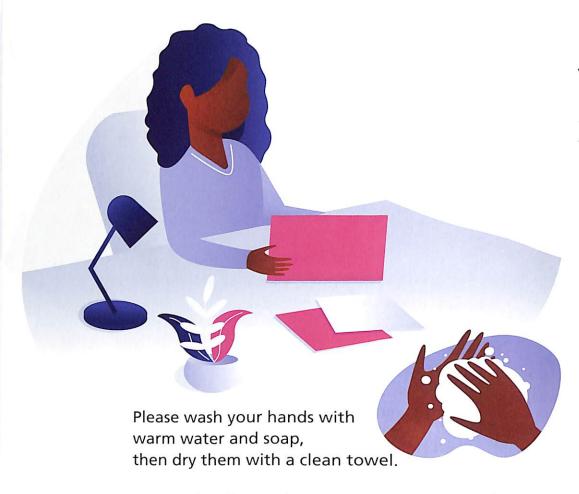
Please follow the instructions carefully.

Do

- Read through this full instruction booklet before starting.
- ✓ Find a clean space on a table well away from children and pets to take the test.
- ✓ Give yourself about 30 minutes from start to finish to complete the test.
- ✓ Wash your hands thoroughly with soap and water before and after using the test kit.
- Straight after completing the test, follow Steps 6 & 7, do the questionnaire and upload a photo of the result.
- Safely dispose of the kit as outlined in this booklet.

Don't

- Do not allow children or pets to touch or access the test kit.
- Do not eat or swallow any part of the kit.
- ➤ Do not take any action as a result of the test. This is for research purposes only.
- > Do not give the test to anyone else. This test is only to be done by the person it was sent to.



Now make plenty of space on a clean table, then lay out the pieces of the test kit in front of you.

Take the testing stick out of its foil wrapper and arrange the pieces of the test kit on your table.

You may notice the testing stick has a blue line next to 'C' – this is normal.

Arrange the various pieces of the test kit on a clean area of a table:



Alcohol wipe



Two lancets, each with a protective cap over the needle



Testing stick, taken out of foil wrapper



Buffer liquid



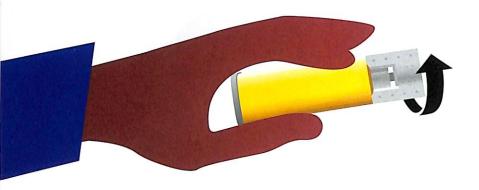
Timer or clock (not included)



The included pipette may be used if you choose

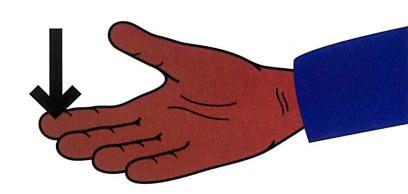
Hold the yellow lancet and twist the cap one full turn to unlock, then pull the cap until you feel it separate from the device. Remove the cap completely.

You can dispose of the cap.





Lancet



Next, choose a spot on the fleshy bit or side of one finger as pictured here.

Wipe the area on your finger with the alcohol wipe.

If you are right handed it may be easiest to choose a spot on your left hand and vice versa.



Alcohol wipe

To draw blood, press the uncapped end of the lancet firmly against your wiped finger until you hear a click.

This will feel like a little pinch and will create a droplet of blood.





Uncapped lancet

Important: please read

Do not tamper with the lancet. If the lancet malfunctions, use the spare lancet.

The lancets are sterile and designed for this purpose. If you fail to get a drop of blood using the lancets provided, do not attempt to draw blood with any other device.

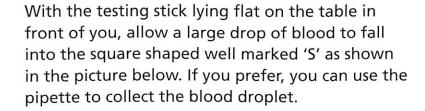






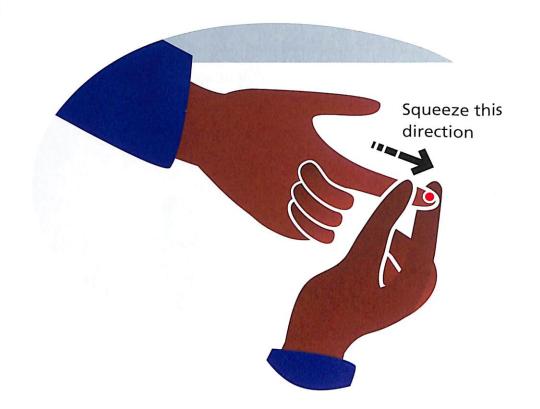
Step 5

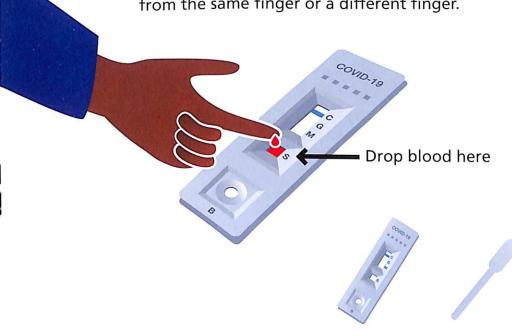
Squeeze your finger from the base of your finger towards the fingertip. This will move the blood towards where you pricked your finger. Do this until you form a large droplet of blood.



Be sure the blood covers the bottom of the well. The test will not work properly if not enough blood is dropped in.

If you don't get enough blood, repeat the prick with the orange lancet provided. You can do this from the same finger or a different finger.

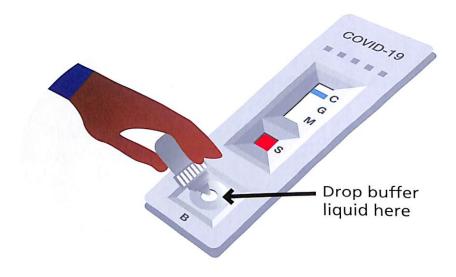


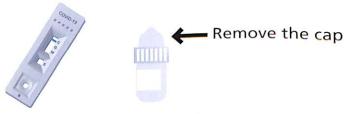


Testing stick

Pipette

Remove the cap from the buffer liquid container and add two drops to the circular well at the bottom (marked 'B') as shown in the picture below.





Testing stick Buffer liquid

Step 7

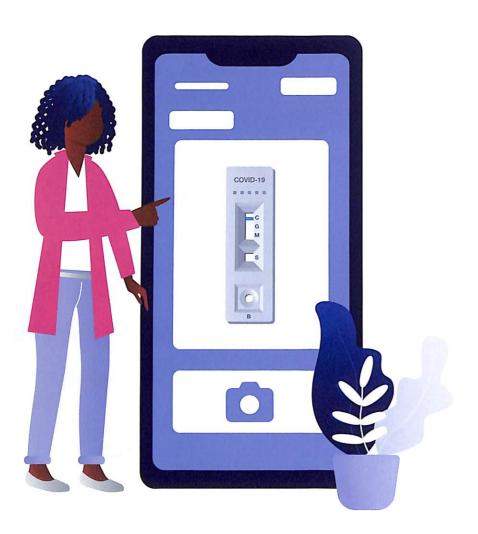
Once the buffer liquid has been added, wait for 10 minutes but no longer than 15 minutes before reading the result (see page 21) and taking a photo (Read Step 8).

If after two minutes the blue line has not turned red, add one additional drop of buffer liquid to the buffer well (marked 'B').



Timer or clock (not included)

We need you to share your test result with us as part of this research study.



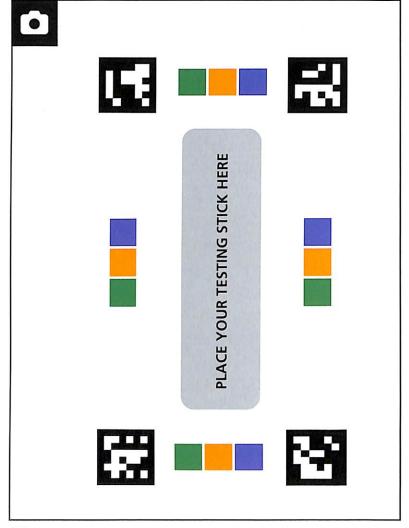
When taking a photo of your result, please use the **template provided** on the next page.

You can choose to upload the photo when you complete the online questionnaire in Step 9.

16

Photo template

"Place your testing stick on the **grey space** and take a photo from directly above in a well-lit area. Avoid any shadows in the photo and do not use a flash. Use the black **border** as a guide for the edges of your photo."



Good testing stick photos

This is an example of a sharp photo from directly above with good lighting, using the template provided.





Bad testing stick photos

These are examples of invalid photos.











Please visit www.reactstudy.org/antibodytest

Enter the access code found on the letter in the test pack. Complete the questionnaire and upload the photo of your testing stick when prompted.

The results may fall into three categories, Invalid, Negative or Positive. Please review the images on the facing page to find the one that matches the pattern that has appeared on your testing stick.

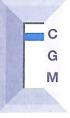
This test is only for research purposes

Please be aware that the antibody test is not reliable at an individual level. Therefore, whatever your test result, you must continue to follow current Government advice.

What do the results mean?

Antibodies are made by the immune system to fight infection. This test looks for two types of antibodies, IgM ('M' line), which don't stay in the body very long, and IgG ('G' line), which are usually longer lasting. By looking for antibodies in your blood, we can understand whether someone has previously been infected with the virus that causes COVID-19.

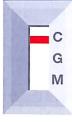
Invalid test result



Your test result is invalid if the line next to 'C' is still completely or partially blue, whether or not there are other visible lines next to 'G' or 'M'.

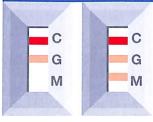
This means the test has not worked and no result can be given.

Negative test result



Your test result is negative if the line next to 'C' is completely red and there are no lines next to 'G' or 'M'.

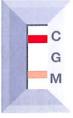
IgG positive test results



Your test result is positive if the line next to 'C' is completely red and there is a line (no matter how light or dark) next to 'G' or 'G' and 'M'.

21

IgM positive test result



Your test result is positive if the line next to 'C' is completely red and there is a line (no matter how light or dark) next to 'M'.

This test is only for research purposes

This test is not reliable at the individual level so please do not change your behaviour whatever the result. We do not yet know if having antibodies against coronavirus protects people from getting COVID-19 again.

Step 10

You have now completed the test and can safely dispose of the test kit. Please do the following:

Disposal of the test kit

- Place the testing stick back into its foil wrapper.
- Place all of the test kit items into the plastic case they came in.
- Dispose of the kit with your regular household waste
- Keep out of reach of children and pets.

If you choose not to complete the test, you should dispose of the kit following the instructions above.

Safety precautions:

- In case of accidental skin exposure to the buffer liquid, wash the exposed area with soap and water.
- In case of accidental eye exposure to the buffer liquid, rinse the eyes thoroughly with cool water.
- If irritation or any other symptoms develop after accidental ingestion or exposure to the buffer liquid, call NHS 111 to seek medical advice.



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Freephone help desk: 0800 819 9150

Manufacturer: Fortress Diagnostics Ltd, 9A The Technology Park, Belfast Road, Antrim, BT41 1QS.